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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Applicant	:	Gopi M. Venkatesh
Serial No.	:	10/658,078
Filed	:	September 9, 2003
Title	:	EXTENDED RELEASE SYSTEMS FOR MACROLIDE ANTIBIOTICS
Docket	:	451194-092
Examiner	:	Yong Soo Chong
Art Unit	:	1617

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

This request is filed in response to the final Office action dated February 8, 2006, and the Advisory Action dated June 26, 2006. According to the Advisory Action, the period for reply expires four months from the mailing date of the final rejection. Accordingly, applicants hereby request a two-month extension of time and enclose the applicable fee. The Director is hereby authorized to charge any additional fees which may be required to Deposit Account No. 20-0809.

Claims 1-14 remain in this application. Claims 10-12 have been withdrawn. Claims 1-9 and 13-14 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention. Applicants submit that the rejections of record are clearly not proper and request that the rejections be withdrawn.

The claims of the present application are directed to an oral solid pharmaceutical dosage form comprising an extended release tablet wherein the tablet comprises a macrolide antibiotic, 2-40% of one or more water soluble excipients, one or more tableting aids, wherein the dosage form provides a certain dissolution profile. Unlike conventional extended release dosage forms, the claimed dosage form does not contain a dissolution rate controlling polymer. According to the Office action, the term "dissolution rate controlling polymer" is indefinite because any polymer would reasonably be expected to affect the dissolution rate and there is no clear definition in this specification as to what a "dissolution rate controlling polymer" is. Furthermore, in the Advisory Action, the Office cites case law holding that "a chemical composition and its properties are inseparable" and concludes that "a polymer and its properties are inseparable." However, this conclusion fails to take into account the fact that polymers can be provided in various grades that can vary in viscosity and substitution. Applicants respectfully submit the same type of polymer can have very different physical properties and uses depending upon the specific characteristics of the polymer. For example, hydroxypropyl methylcellulose (HPMC) can be used as a coating agent, film former, binder, viscosity-increasing agent or rate controlling polymer, but there are different grades that are used for different functions. A person of ordinary skill in the art can readily identified which specific types or grades of polymer are suitable for a particular purpose.

Applicants submit that the term "dissolution rate controlling polymer" is a term of art known to those of ordinary skill in the art and, therefore, an expressed definition of the term is not required in the specification. It is not necessary to define a term that one of ordinary skill in the art would understand when the term is viewed in the context of the specification. See *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 780 (Fed. Cir. 2002). Dissolution rate controlling polymers are well known to those of ordinary skill in the art as high viscosity polymers widely used in the matrix tablet formulations to control release of an active ingredient.

There are numerous examples of tablet formulations which although contain a binder such as corn starch, povidone, low viscosity HPMC, provide rapid release of the drug under in

vitro dissolution conditions or upon oral administration. To achieve SR profiles, one or more dissolution rate controlling polymers and or fatty acid esters are required to be incorporated into the tablet matrix or bead, pellet or tablet cores are required to be coated. A few examples are presented below with the dissolution rate controlling polymer in BOLD print:

Ultram®, tramadol hydrochloride (a synthetic opioid analgesic) tablets, from Ortho-McNeil Pharmaceuticals, contain corn starch, lactose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate (disintegrant), as inactive ingredients and are film-coated (hypromellose (HPMC), polyethylene glycol, polysorbate 80, titanium dioxide and wax). These are IR (immediate release) tablets. Extended Release Tramadol Tablets from Biovail Laboratories contain lactose, **ethylcellulose (Surelease** @ 25% solids), cetostearyl alcohol, magnesium stearate and talc as inactive ingredients and are further film-coated with HPMC (Methocel E15), HPMC (Methocel E5), Opaspray 33% solids), polyethylene glycol 400, and talc (US Patent 6,254,887).

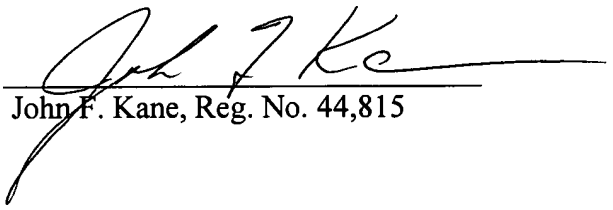
Lamictal®, Lamotrigine Tablets from GSK (US Patent 4,602,017) contain povidone, lactose, microcrystalline cellulose, sodium starch glycolate, and magnesium stearate as inactive ingredients. In accordance with US 2004/0192690, lamotrigine matrix tablets providing up to 16 hour release profiles (see Figures 7 to 9 and Examples 1-2) contain **HPMCs of different viscosities (combinations of Methocel E4M** and Methocel K100) as dissolution rate controlling polymers in addition to the inactive ingredients listed for IR tablets.

The Office further contends that any polymer would have some effect on the dissolution rate of a composition. However, claim terms must be construed as one of ordinary skill in the art would construe them and such a stretched reading of the claims to include any polymer that would have any effect however small on the dissolution rate as being a dissolution rate controlling polymer is inconsistent with proper construction of the claims. Therefore, applicants respectfully submit that the term "dissolution rate controlling polymer" is not indefinite, but instead is a well established and commonly understood term known to those of ordinary skill in the art. Accordingly, applicants respectfully submit that the rejection under 35 U.S.C. §112, second paragraph, is improper and should be withdrawn.

Claims 1-9 and 13-14 stand rejected as being anticipated by or obvious over Rampal et al. (WO 03/017981). However, applicants submit that the claims once properly construed to afford weight to the dissolution rate controlling polymer are novel and non-obvious over the cited references. Rampal et al. clearly disclose the use of dissolution rate controlling polymers in the disclosed dosage forms. The claims of the present application, by contrast, refer to a dosage form that does not contain a dissolution rate controlling polymer. Once this limitation is afforded the proper weight in evaluating the patentability of the claims, these claims clearly distinguish over the disclosure in Rampal et al. Therefore, since Rampal et al. failed to disclose or suggest a dosage form that does not contain a dissolution rate controlling polymer, there can be no anticipation. Therefore, applicants respectfully submit that the rejection is improper and should be withdrawn.

In view of the foregoing, it is respectfully submitted that the rejections of record are clearly not proper and that the claims currently pending are in compliance with 35 U.S.C. §112, second paragraph, and are distinguishable from the cited documents and are in condition for allowance. Applicants respectfully request that a Notice of Allowability be issued in this case.

Respectfully submitted,



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